

**Major Intellectual Property issues faced from a
contracting/research partnership perspective in Africa & other
regions**

COHRED Fair Research Contracting Meeting at Bellagio Center, 22-26
October 2012

**Professor Pamela Andanda,
School of Law,
University of the Witwatersrand,
Johannesburg
E-mail: Pamela.Andanda@wits.ac.za**

Overview

1. Relevance of IP in the research contracting/partnership context:

a) Trends from current literature

b) Trends from WIPO Report (2011)

2. Specific IP issues

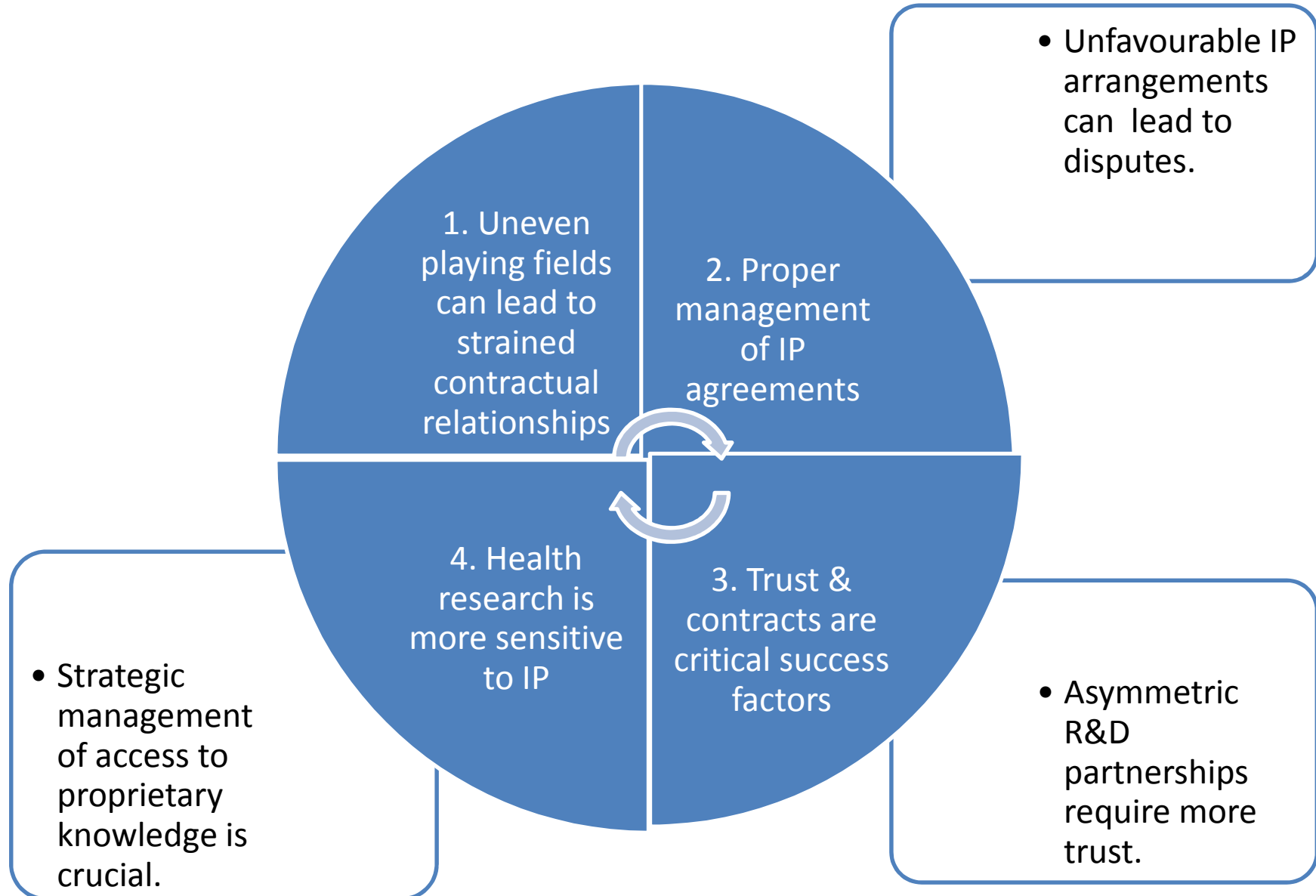
3. Some thoughts on the way forward

1. Relevance of IP in the research contracting/partnership context

Considerations:

- Uneven playing fields between collaborators from LMICs and high income countries
- lack of legal frameworks to effectively manage IPRS

a) Trends from current literature:



b) Trends from WIPO Report

(*World Intellectual Property Report: the Changing Face of Innovation*, WIPO Economics & Statistics Series (2011))

Key factors	Impact on research contracts
1. Increased focus on knowledge and the rise of new innovating countries, coupled with the desire to protect inventions abroad;	a growing demand for IP protection
2. Collaborators are increasingly innovative when collaborating with universities;	while fostering cooperation, collaborators also ensure control by insisting on royalty-free licence on any university patent emerging from research that they have funded

2. Specific IP issues



a. Exclusive ownership of intellectual property;

b. Exclusive data ownership;

c. Specimen/sample ownership;

d. Disagreements over dispute resolution.

Ref. D Sack *et al.*, “Improving international research contracting”, *Bull World Health Organ* (2009) 87:000–000
doi:10.2471/BLT.08.058099

a) Exclusive ownership of intellectual property

Underlying reasons:

- The emergence of knowledge markets based on IPRS; IP is therefore viewed as a vehicle for knowledge transfer and protection. (WIPO Report 2011, p.52)
- Stronger IP protection, especially in many developing countries that “justify stronger IPRS by claiming that this policy will result in greater inward flows of technology, a flowering of local innovation and cultural development, and faster ability to close the gap in technological sophistication between themselves and rich countries”. (Maskus, 2000, p.199)

South African example of IP protection :

Intellectual Property Rights from Publicly Financed R&D Act (2008), which requires that intellectual property emanating from publicly financed R&D be identified, protected, utilized and commercialized for the benefit of the people of South Africa.

South African example of IP protection (cont.):

An unintentional introduction of a two-edged sword in the regulation of research;

“A recipient that prefers not to retain ownership in its intellectual property or not to obtain statutory protection for the intellectual property must:

(a) make the choice in accordance with the regulations and any guidelines published by [the National Intellectual Property Management Office] NIPMO by notice in the Gazette; and

(b) within the period set out in section 5(1) (e), notify NIPMO of the decision and the reasons therefore.” - s4(2)(a) and (b)

Ugandan example of ineffective IP protection:

Low internal patenting causes local scientists to “miss out on country specific knowledge that may be in existence but not recorded or systematized in any way. As a result, much-needed data that can assist the development of the country is not shared and disseminated.” (van Genugten *et al.*, 2011, p.407)

b) Exclusive data ownership

Underlying reasons:

- viewing data as having proprietary value and
- misinterpreting of Article 39.3 of the TRIPS Agreement, which provides as follows:

“Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

Exclusive data ownership (cont.)

The issue of data exclusivity “seems to mark a shift from the conventional debates over patent protection and drug prices... [as it] involves both developed and developing countries, is characterized by political and economic interests, as well as by safety issues that guarantee to make it one of the more interesting as well as heated subjects in the IPR field.”- MP Pugatch 2006,p.129

Correct interpretation of Article 39.3

“... does not create property rights, nor a right to prevent others from relying on the data for the marketing approval of the same product by a third party, or from using the data except where unfair (dishonest) commercial practices are involved.”-WHO Commission on IPRs, Innovation and Public Health (2006)

only confers “the right to take legal action against whoever has obtained commercial advantage by means of dishonest practice.”- (Correa, 2006)

c) Specimen/sample ownership

Rarely viewed as an IP issue because:

- there is a clear distinction between ownership of the samples and ownership of IPRs that may arise from inventions that are derived from the samples- (Andanda, 2008)
- ownership of samples is rarely accorded adequate attention, particularly in developing countries
- Relevant legal frameworks are fragmented and lack focus

d) Disagreements over dispute resolution

Linked to two possible IP-related factors:

- Preference for developed country collaborators' more effective substantive laws and institutions
- Insistence on the partnership being governed by the laws of developed countries rather than those of the LMICs where the research is being conducted (a strategy of indirectly imposing TRIPS-plus standards)

4. The way forward

a) striking “a balance between the needs of information developers and users, with due regard for market externalities that may not be well managed, and could be exacerbated, in a framework of strong IPRS.”-(Maskus 2000,p.200)

b) shifting the default position from data confidentiality to one of disclosure

c) empowering research institutes and research governance bodies in LMICs

Thank you!!